

A biologic graft supported by data

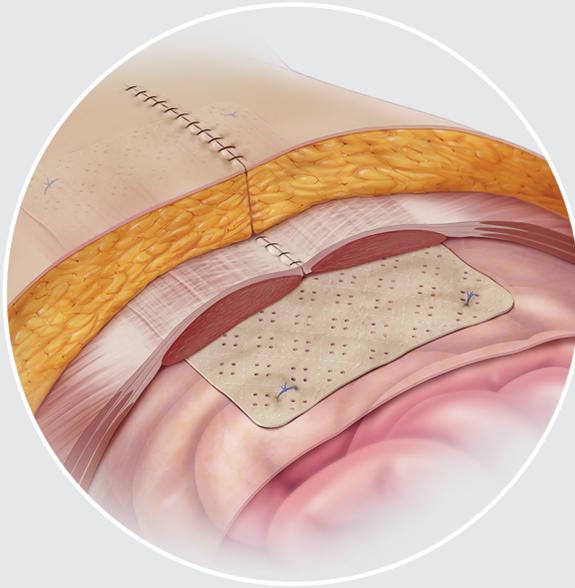


Biodesign[®]
ADVANCED TISSUE REPAIR



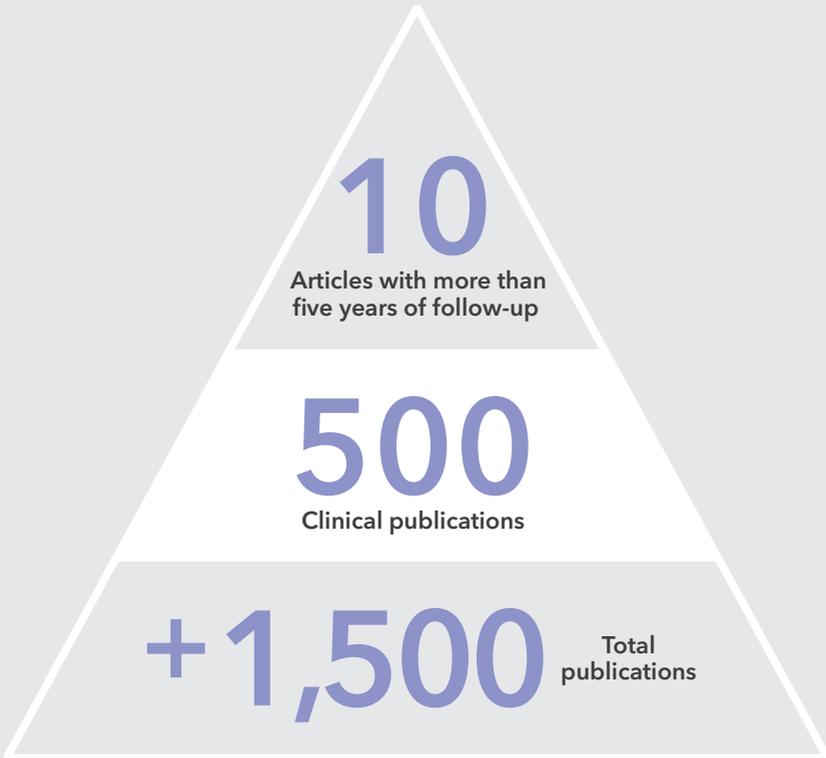
Biodesign® Hernia Graft

The Biodesign Hernia Graft is a non-cross-linked, non-dermis biologic graft that is completely remodelled into strong, vascularised patient tissue.¹⁻³



Studied and proven

The technology behind Biodesign® tissue-repair products is supported by more than 1,500 total publications. More than 500 of those describe clinical use. And 10 of those have more than five years of follow-up data.



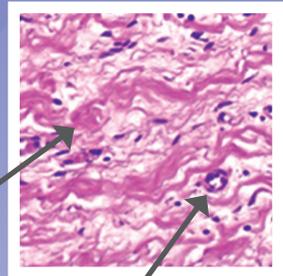
Are all biologic grafts the same?

No. Some biologic grafts are associated with **higher rates of failure.**⁴

Biodesign® Hernia Graft is a **non-dermis, non-cross-linked** graft.⁴

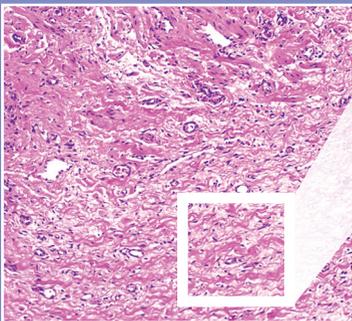
Non-Dermis

As a non-dermis graft, the Biodesign Hernia Graft contains no meaningful amounts of elastin.⁴ Dermis-based biologic grafts contain high amounts of elastin. Studies attribute higher rates of failure to higher elastin levels.^{5, 6}



Organised collagen

No meaningful amounts of elastin



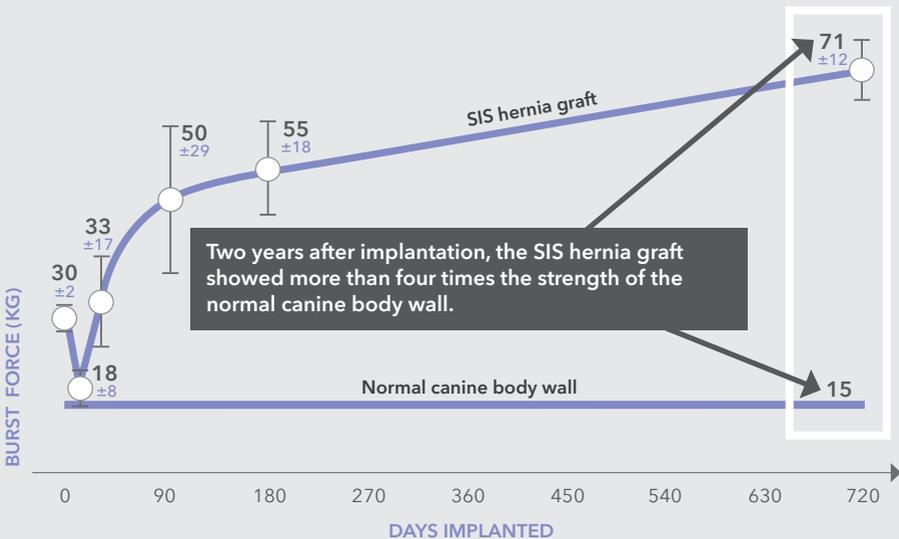
Non-cross-linked

The technology behind Biodesign Hernia Graft has been designed to maintain strength throughout the remodelling process, so there is no need for chemical cross-linking.³ Cross-linked grafts have been associated with chronic inflammation and encapsulation.⁷

Strength

The Biodesign® Hernia Graft is specifically designed to provide strength during the repair and remodelling of a hernia or body wall defect. It is sourced from porcine small intestinal submucosa (SIS), a naturally occurring biomaterial.

Preclinical data have shown long-term strength as SIS remodels.³

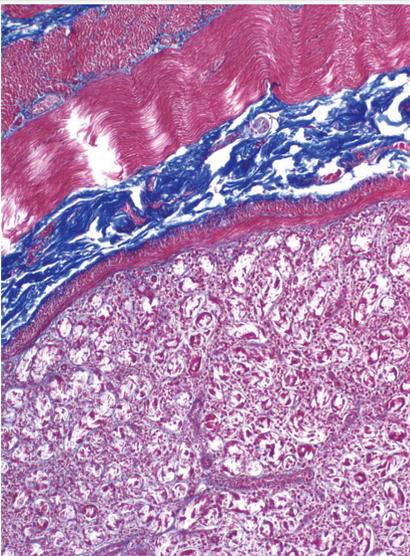


Not only is the graft strong at the time of implant, it is designed to exceed the strength of the normal abdominal wall during the time it is being remodelled into vascularised tissue. When tissue repair and remodelling are complete, the resulting tissue is stronger than that which was implanted. No permanent material is left in the subject's body.³

Are all biologic grafts the same?

No. Over time, the Biodesign® source material remodels completely into new patient tissue—letting the body’s own defence mechanisms fight infection naturally.⁸

The Biodesign Hernia Graft is sourced from porcine small intestinal submucosa (SIS). The material acts as a scaffold that, once implanted, allows the patient’s cells to **infiltrate and remodel into vascularised patient tissue.**¹⁻³



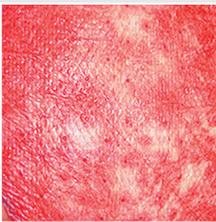
Small intestinal submucosa supports one of the harshest environments in the body and supports rapid cell turnover.⁹

Biodesign source material

Tissue remodelling

Once it's implanted in the body, the Biodesign® source material helps the patient's own cells infiltrate the scaffold and remodel the material into natural patient tissue.¹⁻³

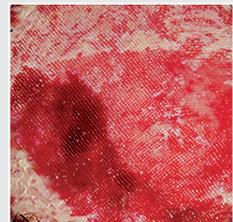
Biodesign becomes remodelled by the body over a period of several weeks.



Day 0 - Implanted



Day 7 - Cells migrate and proliferate into the material and begin to form blood vessels.



8 weeks - Granulation tissue bed has formed.

Images used with permission from Prof. Mohammed Ballal, MD.

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- ¹ Franklin ME Jr, Treviño JM, Portillo G, et al. The use of porcine small intestinal submucosa as a prosthetic material for laparoscopic hernia repair in infected and potentially contaminated fields: long-term follow-up. *Surg Endosc.* 2008;22(9):1941-1946.
 - ² Nihsen ES, Johnson CE, Hiles MC. Bioactivity of small intestinal submucosa and oxidized regenerated cellulose/collagen. *Adv Skin Wound Care.* 2008;21(10):479-486.
 - ³ Badylak S, Kokini K, Tullius B, et al. Strength over time of a resorbable bioscaffold for body wall repair in a dog model. *J Surg Res.* 2001;99(2):282-287.
 - ⁴ Hiles M, Record Ritchie RD, Altizer AM. Are biologic grafts effective for hernia repair?: a systematic review of the literature. *Surg Innov.* 2009;16(1):26-37.
 - ⁵ Gupta A, Zahriya K, Mullens PL, Salmassi S, Keshishian A. Ventral herniorrhaphy: experience with two different biosynthetic mesh materials, Surgisis and Alloderm. *Hernia.* 2006;10(5):419-425.
 - ⁶ Kissane NA, Itani KMF. A decade of ventral incisional hernia repairs with biologic acellular dermal matrix: What have we learned? *Plast Reconstr Surg.* 2012;130(5 Suppl 2):194S-202S.
 - ⁷ Novitsky YW, Rosen MJ. The biology of biologics: basic science and clinical concepts. *Plast Reconstr Surg.* 2012;130(5 Suppl 2):9S-17S.
 - ⁸ Poulouse BK, Scholz S, Moore DE, et al. Physiologic properties of small intestine submucosa. *J Surg Res.* 2005;123:262-267.
 - ⁹ Children's Hospital Los Angeles. Controlling cell turnover in the intestinal lining. *Science Daily.* <https://www.sciencedaily.com/releases/2016/04/160405182950.htm>. Published April 5, 2016. Accessed June 19, 2018.

Biodesign® Hernia Graft

Used for implantation to reinforce soft tissues where weakness exists during ventral hernia repair.

Order Number	Reference Part Number	Size cm
G57513	C-SLH-8H-10X10-2	10 x 10
G57514	C-SLH-8H-13X15-2	13 x 15
G57515	C-SLH-8H-13X22-2	13 x 22
G57516	C-SLH-8H-20X20-2	20 x 20
G57517	C-SLH-8H-20X30-2	20 x 30

Some products or part numbers may not be available in all markets.

BIODESIGN® HERNIA GRAFT

INTENDED USE: The Cook® Biodesign® Hernia Graft is intended for implantation to reinforce soft tissues where weakness exists during ventral hernia repair. The graft is supplied sterile and is intended for one-time use. **[Rx ONLY]** This symbol means the following: **CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.** **[MR]** This symbol means the following: Magnetic Resonance Safe. **[HERNIA GRAFT]** This symbol means the following: Hernia Graft. This graft is intended for use by trained medical professionals.

CONTRAINDICATIONS: This graft is derived from a porcine source and should not be used in patients with known sensitivity to porcine material.

PRECAUTIONS: • This device is designed for single use only. Attempts to reprocess, resterilize, and/or reuse may lead to device failure and/or transmission of disease. • Do not resterilize. Discard all open and unused portions of the graft. • The graft is sterile if the package is dry, unopened and undamaged. Do not use if the package seal is broken. • Discard graft if mishandling has caused possible damage or contamination, or if the graft is past its expiration date. • Ensure that graft is rehydrated prior to cutting, suturing, stapling, tacking or loading of the graft laparoscopically. • Ensure that all layers of the graft are secured when suturing, stapling, or tacking. • Place graft in maximum possible contact with healthy, well-vascularized tissue to encourage cell ingrowth and tissue remodeling. • Suturing, stapling, or tacking more than one graft together may decrease graft performance. • No studies have been conducted to evaluate the reproductive impact of the clinical use of the graft. • Extended rehydration or excessive handling could lead to partial delamination of superficial layers of the graft. • Care should be taken when device is placed in infected wounds. • Care should be taken to avoid damage to the graft when loading laparoscopically. It is recommended to load through a 10 mm or larger port. • If wound is left open, keep graft moist to prevent dryness.

POTENTIAL COMPLICATIONS: Possible adverse reactions with the use of biologic hernia prostheses may include: • adhesion • allergic reaction • bowel erosion • bowel obstruction • discharge • fever • fistula formation • hematoma • hernia recurrence • infection/abscess formation • inflammation • pain • premature degradation • seroma formation • wound dehiscence

See package insert for full product information.

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